November 3, 2016

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

Re: FOIA Request, Protection of Human Subjects

Dear EPA FOIA Officer,

Under the federal Freedom of Information Act (FOIA), 5 U.S.C. § 552, CropLife America (CLA) requests all reasonably segregable, nonexempt portions of "documents" that the Environmental Protection Agency (EPA or the Agency) has in its possession or control relating to any determination by the Agency that the Columbia Center for Children's Environmental Health (Columbia University) epidemiology cohort studies of inner-city mothers and children concerning pre- and post-natal pesticide exposure to chlorpyrifos and other organophosphate pesticides (hereinafter, the Columbia Study) complies with the Agency's policy for protection of human subjects, 40 C.F.R. § 26.101, *et. seq*.

According to EPA's own regulations, the use of human subjects in EPA-funded studies must meet strict protective standards, especially with regard to pregnant women and children. *Id.* In fact, EPA has instituted additional protections, beyond those agreed upon by the various federal agencies, for pregnant women and children used as subjects in EPA observational research. EPA has stated that it is committed to using those studies done in reliance on scientifically sound research that is ethically conducted. *See* https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/protections-subjects-human-research-pesticides. This request seeks information to assure the public that EPA has held itself to this high standard in funding and using the Columbia Study in pesticide risk assessments.

For purposes of this FOIA request, the term "documents" means all written, typed or otherwise preserved materials or "communications," including any letter, facsimile, email, text message, note, book, pamphlet, article, bulletin, directive, review, publication, memorandum, presentation, diary, log, test analysis, study, sample, schematic, contract, agreement, work paper, calendar, envelope, telephone message and all other writings. For purposes of this request, "communications" means any oral, written or electronic transmission of information without limitation. Examples of communications include, but are not limited to meetings, discussions, conversations, telephone calls, memoranda, letters, email messages, text messages, conferences, seminars, or notes. Communications include transmission of information via personal or unofficial email accounts and other C communication mediums.

The timeframe for documents and communications responsive to this request is from January 1, 2004 through the present.

1. All documents and communications between current or former EPA staff and any current or former Columbia University staff pertaining to Columbia University's application for research grants and other funding for the Columbia Study.

2. All documents and communications between current or former EPA staff and the following individuals (hereinafter, the Columbia Study Authors) pertaining to the protection of human subjects used in the Columbia Study:
    a. Virginia Rauh
    b. Robin Whyatt
    c. David E. Camann
    d. Frederica P. Perera
    e. Deliang Tang
    f. Howard Andrews
    g. Robin S. Garfinkel
    h. Srikesh Arunajadai
    i. Megan Horton
    j. Lori Hoepner
    k. Dana B. Barr
    l. Ralph Whitehead
    m. Diurka Diaz
    n. Jessica Dietrich
    o. Andria Reyes
    p. Patrick L. Kinney

3. All documents and communications regarding any determination by EPA that the Columbia Study complied with the Agency's requirements under 40 C.F.R. § 26.101, *et.seq.*, for the protection of human subjects for research supported by the Agency.

4. All documents and communications pertaining to any determination by EPA that the Columbia Study was "observational research," defined in EPA Order 100.17A as involving "neither the deliberate exposure of participants nor the control of environmental conditions in a way that impacts the participants' naturally occurring exposures."

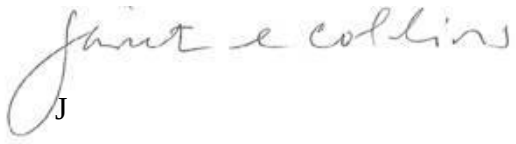
5. All documents and communications between current and former EPA staff and the Columbia Study Authors (see 2, above) pertaining to:
    a. Whether pesticide exposure experienced by the human subjects participating in the Columbia Study would not have occurred but for the human subject's participation in the study;
    b. The pesticides to which the human subjects were exposed; and
    c. Dates and locations of any and all pesticide applications relevant to the Columbia Study.

6. All documents and communications pertaining to records submitted by the Columbia Study Authors (see 2, above) to the Agency under 40 C.F.R. § 26.103, *et. seq.*, including:
    - A statement of principles governing Columbia University in assuring the protection of human subjects participating in the Columbia Study;
    - The designation of one or more Institutional Review Boards (IRBs);
    - A list of IRB members including education, area of expertise, any potential conflicts of interest and any prior relationships between any member of the IRB and Columbia University;
    - Written procedures for the IRB;
    - Written procedures for ensuring prompt reporting to the IRB and EPA of any unanticipated problems involving risk to subjects or others or any serious or continuing noncompliance with 40 C.F.R. § 26.103;
    - Written determination that the collection of maternal blood or cord blood at delivery involved the least possible risk for achieving the objectives of the study;
    - Written determination that the risk of invasive blood collection was justified; and
    - Written determination that the collection of cord blood at delivery did not produce greater than minimal risk.

CLA is willing to pay fees for this request up to a maximum of $1000. If you estimate that the fees will exceed this limit, please inform me before processing this request. We prefer to receive the information electronically in PDF file format if possible, and request that any responsive materials be released to CLA on a rolling basis. CLA reserves its right to appeal any denial of this request.

If you have any questions regarding this request, please contact me at 202-833-4474 or jcollins@croplifeamerica.org. I look forward to receiving your response within the twenty-day statutory time period. Thank you for your assistance with this matter.

Sincerely,



J

Janet E. Collins, Ph.D.
Senior Vice President, Science & Regulatory Affairs
CropLife America